

Tuberculosis Control Program Drug Management Information System Assessment

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May 2005

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Supported by the U.S. Agency for
International Development

This document was made possible through support provided by the U.S. Agency for International Development, under the terms of Cooperative Agreement Number HRN-A-00-00-00016-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

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Recommended Citation

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Burn, R. 2005. *Tuberculosis Control Program Drug Management Information System Assessment*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

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CONTENTS

Section 1. Pharmaceutical Sector Profile with Emphasis on Tuberculosis.....	1
Section 2. Tuberculosis Program Profile.....	5
Section 3. Drug Policy, Legislation, Regulation, and Registration	9
Section 4. National Drug Regulatory Authority Questionnaire.....	12
Section 5. Selection, Quantification and Procurement	15
Section 6. Distribution, Transport, Inventory Management and Drug Availability	19
Section 7. Anti-TB Drugs Rational Use	23
Section 8. Anti-TB Drugs Quality Assurance	25
Section 9. Drug Management Information and Information Systems	29

**Tuberculosis Control Program
Drug Management Information System Assessment**

Section 1. Pharmaceutical Sector Profile with Emphasis on Tuberculosis

Documents required: assessment reports

Key indicators:

Respondents: key national level agencies – MOH, National Drug Regulatory Agency, National Health Insurance Agency

Name	Agency	Position/Title

Key Organizations:

1.1. Governmental

- 1.1.1. Which government ministries are involved in regulating, overseeing, or controlling the pharmaceutical sector?

1.2. Local Manufacturing:

- 1.2.1. What is the pharmaceutical sector's organizational structure?
- 1.2.2. What is the pharmaceutical sector's regulatory structure?
- 1.2.3. What is the ownership structure: private/public by types of activities (manufactures; distributors; medical stores)?
- 1.2.4. How many public health facilities dispense anti-TB medicines?
- 1.2.5. How many private pharmacies dispense anti-TB medicines to the general public?
- 1.2.6. How many licensed pharmacists or pharmacy technicians are there in the public sector?

- 1.2.7. How many authorized prescribers in the public sector?
- 1.2.8. How many authorized prescribers in the private sector?
- 1.2.9. What is the minimum wage? If not available, what is the annual salary of the lowest level government employee?
- 1.2.10. List the NGOs that are involved in providing TB health services to the population. Indicate the services they provide and their location?
- 1.2.11. Which NGOs purchase anti-TB drugs and supplies?

1.3. Human Resources

- 1.3.1. What key occupations are involved in pharmaceutical sector: pharmacists; clinical pharmacologists; nurses; medical doctors; IT specialists; managers; etc.?
- 1.3.2. What is known about informal providers of these goods and services?
- 1.3.3. Are there short or excessive labor resources in particular professional groups of the sector?
- 1.3.4. What training is required for obtaining and keeping positions?
 - 1.3.4.1.1. Pre-service training
 - 1.3.4.1.2. In-service training
 - 1.3.4.1.3. Continuous studies
 - 1.3.4.1.4. Other
- 1.3.5. What are the requirements for licensing and certification of human resources?
- 1.3.6. What is the role of the MOH in managing human resources in the sector? In planning? In training? In regulating? In recruiting? In licensing?
- 1.3.7. What is the role of the National Medicine Agency in human resources?
 - 1.3.7.1.1. In setting professional requirements?
 - 1.3.7.1.2. In regulating and executing licensing and certification?

1.4. Market Information

- 1.4.1. What size, reliability, and preference of public and private sector anti-TB drug markets:
 - 1.4.1.1. Of manufacturing market and existing local production capacity (competition)?

1.4.1.2. Of supply market?

1.4.1.3. Of retail market?

1.4.2. What market entry regulation (licensure?) is in place?

1.4.3. What are barriers to imported products (degree of protection)?

1.4.4. Are prices regulated or there is price competitive market?

1.4.5. What are major market trends?

1.4.6. Any problems in regard to shadow market(s)?

1.5. Drug Financing

1.5.1. What are main sources of funding?

1.5.2. What is actual composition of funding: health insurance; MOH budget; out of pocket (households)?

1.5.3. How does the population participate in cost-sharing?

1.5.4. Are there any price regulations involved?

1.5.5. What has been the financial requirement for anti-TB drug supply for the last 3 years?

1.5.6. What funds have been available for anti-TB drug supply for the last 3 years?

1.5.7. What is the balance between requirements and actual funding for the last 3 years?

1.5.8. What is the actual value of inventory of anti-TB drugs? When it was last recorded?

1.5.9. How geographical allocation of funds is organized and executed?

1.5.10. Where and how data on financing are recorded and reported?

1.6. TB Health Service Delivery

1.6.1. What is provider composition: public, private, NGOs; other sector related (prisons); informal provision?

- 1.6.2. Is TB diagnostics and treatment included into public programs?
- 1.6.3. What percentage of TB patients has access to health services?
- 1.6.4. What percentage of TB patients has access to smear microscopy tests?
- 1.6.5. Are TB patients' referrals regulated?
- 1.6.6. What clinical guidelines are adopted in the country (DOTs, not DOTs, other)?
- 1.6.7. Is service quality assurance regulated and practiced?

1.7. TB Health Service Utilization

- 1.7.1. What are reported utilization indicators (e.g. doctor visits, lab tests, hospital admissions, etc)?
- 1.7.2. (Acquire major data on per capita utilization: morbidity; notification rates, detection rates; cure rates; etc.)
- 1.7.3. Do service utilization data contain drug use?
- 1.7.4. Are there any indicators associated with patients' drug use adherence (# of dropped treatment cases, relapse rates)?

1.8. Information system

- 1.8.1. Are there pharmaceutical information systems?
- 1.8.2. What part of pharmaceutical IS contains information on anti-TB drugs?
- 1.8.3. How is this pharmaceutical IS are managed and administered?
- 1.8.4. Is there a centralized bank of information on pharmaceutical sector?
- 1.8.5. See also section 8 on TB DMIS.

1.9. What do interviewees consider important to be addressed in TB pharmaceutical sector to improve its capacities, effectiveness, efficiency and other major determinants of a well functioning system?

Tuberculosis Control Program Drug Management Information System Assessment

Section 2. Tuberculosis Program Profile¹

Documents Required: NTP strategy; NTP organizational structure;

Key indicators

Ministry of Health budget or expenditures on anti-TB drugs, US\$ per TB patient (specify year)

Other institutions budget or expenditures on anti-TB drugs, US\$ per TB patient

Judet budget or expenditures on anti-TB drugs, US\$ per TB patient

The percentage of TB patients covered by any government program

The percentage of TB patients covered by any private program

Respondents: Key national level agencies – MOH, National Medicine Agency, Institute of Tuberculosis; Manager of a National TB program

Name	Agency	Title

2.1. General Information

2.1.1. What (standard) treatment regimens are approved and used for the following types of TB?

2.1.1.1. Category I

2.1.1.2. Category II

2.1.1.3. Category III

2.1.2. Please estimate the percentage of cases on each regimen during the past year or for :

2.1.2.1. Smear positive pulmonary (new)

2.1.2.2. Smear positive pulmonary (relapse/failure)

2.1.2.3. Smear negative pulmonary/extra pulmonary

2.1.2.4. Chronic cases

2.1.2.5. MDR-chronic

2.1.2.6. Chronic full sensibility

¹ This section is developed for each TB program if administered separately for a defined population

2.1.2.7. *How many patient are registered:*

2.1.2.8. *How many of them are treated by GPs?*

- 2.1.3. How is provider compliance with the standard treatment regimens monitored?
- 2.1.4. Is the compliance with the standard treatment regimens documented? It is in the checklist
- 2.1.5. Are any anti-TB drugs used that are *not* included in the standard regimens? Please explain.
- 2.1.6. Are fixed dose combination of anti-TB drugs routinely used? If not, are there plans to incorporate them into the standard treatment regimens? Indicate which ones and when.
- 2.1.7. Are blister packs of anti-TB drugs used? If yes, please explain how they are packaged.
- 2.1.8. Are patient kits of anti-TB drugs used? If yes, please explain their contents, how they are prepared, and how they are managed.

2.2. Structure and Organization

- 2.2.1. How is this program organized and administered? (Program organizational chart may be required)
- 2.2.2. What institutions are involved into the program implementation?
- 2.2.3. What are roles of major institutions involved?
- 2.2.4. Is there a defined management framework and clearly assigned management functions in this TB program?
- 2.2.5. Specify authorities.

2.3. Program Policy

- 2.3.1. Is the program's policy specified? What document should be referred to?
- 2.3.2. What population is covered by the program?
- 2.3.3. What are the information management policies of the program?
- 2.3.4. What are planning cycles?
- 2.3.5. How is the program monitored and evaluated?

2.4. Financial, Human and Organizational Resources

2.4.1. Finance:

- 2.4.1.1. How program is funded: sources, principles, regulation?
- 2.4.1.2. Is the program financially sustainable?
- 2.4.1.3. Are there plans to change sources of funding for the program in the new future?
- 2.4.1.4. Do patients participate in payments for services and drugs? If yes, on what principles?
- 2.4.1.5. What is the percentage of out-of-pocket expenditures incurred by TB patients?
 - 2.4.1.5.1. In-patients in TB hospitals?
 - 2.4.1.5.2. Out-patients?

2.4.2. Human resources:

- 2.4.2.1. How many staff are involved in the program?
- 2.4.2.2. What STAFF CATEGORIES OF STAFF are involved: e.g. medical doctors; nurses; pharmacists; managers; economists, IT specialists; others?
- 2.4.2.3. Are there short or excessive labor resources in particular professional groups of the program?
- 2.4.2.4. Are there specific requirements for training to participate in the program?
 - 2.4.2.4.1. Pre-service training
 - 2.4.2.4.2. In-service training computer use training,
 - 2.4.2.4.3. Continuous studies drug procurement training
 - 2.4.2.4.4. Other.
- 2.4.2.5. What are training needs of the NTP?
- 2.4.2.6. What are the requirements for licensing and certification of human resources for this program?
- 2.4.2.7. Who is responsible for human resources in the program?
 - 2.4.2.7.1. In planning?
 - 2.4.2.7.2. In training?
 - 2.4.2.7.3. In regulating?

2.4.2.7.4. In recruiting?

2.4.2.8. Are there any constraints (e.g. legal norms) preventing effective human resource policies and management?

2.4.2.9. Are there performance targets for personnel participating in the program?

2.4.2.10. Are requirements to quality of work or services provided?

2.4.2.11. Is there a system of incentives and enablers in place to motivate personal in attaining performance targets?

2.4.2.12. Are there specific targets and incentives for personnel involved in drug management?

2.5. TB Program Health Service Utilization

2.5.1. What are available utilization indicators (e.g. doctor visits, lab tests, hospital admissions, etc)?

2.5.2. (Acquire major data on per capita utilization: morbidity; notification rates, detection rates; cure rates; etc.)

2.5.3. Does service utilization data contain drug use?

2.5.4. Are there any indicators associated with patients' drug use adherence (e.g. # of dropped treatment cases, relapse rates)?

2.5.5. How many patients are under the supervision of a single TB specialist in general?

2.5.6. How many patients would a GP manage the outpatient treatment?

2.6. Information system and information resources

2.6.1. What information about the program and on the program performance is available?

2.6.2. Also see Section 8.

2.7. What do interviewees consider important to be addressed in TB program to improve its capacities, effectiveness, efficiency and other major determinants of a well functioning program?

Tuberculosis Control Program Drug Management Information System Assessment

Section 3. Drug Policy, Legislation, Regulation, and Registration

Documents Required: National Drug Policy; TB Policy; legal acts; regulatory acts and norms; registration guidelines or regulatory norms

Key indicators:

- Existence of a national TB drug policy
- Existence of enforcement mechanisms
- The percentage of DOTS TB drugs on National EDL/Formulary list
- Existence of regional drug policy and regulation regarding TB drug supply
- Number of TB drugs registered

Respondents: Key national level agencies – MOH, National Medicine Agency, Institute of Tuberculosis; Parliament Committee on Health (if any)

Name	Agency	Title

3.1. Policy, Legislation and Regulation

- 3.1.1. Is there a national drug policy approved by the government? When was this last updated?
- 3.1.2. Is there a comprehensive drug law?
 - 3.1.2.1. Is it a new law or a revision of an existing law?
 - 3.1.2.2. When was this last updated?
- 3.1.3. Is the legislation flexible in allowing for the passage and revision of regulations in response to new scientific information and market changes?
- 3.1.4. Is there a drug regulatory authority responsible for the promulgation of regulations and for enforcement?
- 3.1.5. What parties are involved in policy making and regulation of pharmaceutical products?

- 3.1.6. Are there policies on manufacture, storage, distribution, and sale of pharmaceutical products?

3.2. Drug Registration

- 3.2.1. There is a system of drug registration?
- 3.2.1.1. Is this a notification procedure?
- 3.2.1.2. A basic authorization procedure?
- 3.2.1.3. A full registration procedure?
- 3.2.1.4. Is periodic renewal required?
- 3.3. What are criteria for registration (efficacy, safety, quality, and truth of packaging information)?
- 3.4. Are pharmacological or therapeutical standards used?
- 3.5. Are there different registration procedures for essential drugs, generic products, multisource drugs, or imported drugs from selected countries?
- 3.6. Is the WHO certification scheme on the quality of pharmaceutical products moving into international commerce used systematically for the registration of imported drugs?
- 3.7. Is there a system for the collection of data regarding the efficacy and safety (adverse effects) of marketed drugs?
- 3.8. How easy is a registration process?

Data Element	Data Source	Data Collection Level	Institution Collecting Data	Frequency of Data Collection	Quality of Data
Drug registration guidelines					
Renewal data					

3.9. Compliance and Enforcement

- 3.9.1. What measures exist for enforcement of pharmaceutical laws and regulations?
- 3.9.2. Are they enforceable administratively or through court actions?
- 3.9.3. Are statistics available about compliance and enforcement?

- 3.9.4. During the last three years, how many drug products were eliminated from the register?
- 3.9.5. How many batches of drug products were recalled from the market?
- 3.9.6. Is there a system for reporting drug product problems? What types of and how many complaints were registered in the past three years, and what corrective measures were taken?
- 3.9.7.** Are there any statistics about reaction of the industry and consumers to regulatory actions?

3.10. Information system and information resources

- 3.10.1. Ask questions from section 8 TB DMIS

Tuberculosis Control Program Drug Management Information System Assessment

Section 4. National Drug Regulatory Authority Questionnaire

- 4.1. Which anti-TB drug products are registered in the country? List all the formulations for each drug product by INN and trade name. See attached spreadsheet to collect requested information.
- 4.2. What is the total number of all registered drugs in the country?
- 4.3. Do you require re-registration of drugs? How often?
- 4.4. Are the same pharmaceutical products from different manufacturers individually registered?
- 4.5. Once a pharmaceutical formulation is registered, is separate registration required for each subsequent version of the product (e. different strength and dosage forms)?
- 4.6. Is there a fee to register and re-register a drug in the country? If yes, how much?
- 4.7. What type of management information system is used to manage registered drugs? Manual, computer, both, none. Briefly describe the process.
- 4.8. Which technical documents are required for consideration of an application to register a drug product?
 - 4.8.1. Certificate from regulatory authority of country of origin
 - 4.8.2. Evidence of registration in other countries
 - 4.8.3. Certificate of analysis
 - 4.8.4. WHO type certificate "Certificate of Product Moving In International Commerce"
 - 4.8.5. Clinical trial reports
 - 4.8.6. Others (specify)_____
- 4.9. Describe the NDRA plan for testing all drugs for registration purposes and market surveillance. (Number of drugs to test, facilities where samples are collected).
- 4.10. Describe the laboratory resources: staff capacity, equipment, record systems, access to reagents, reference standards, etc.
- 4.11. Provide the number of drugs actually tested and the results, indicating reason for failure if any.

- 4.12. Describe the NDRA plan for GMP inspection of companies that manufacture anti-TB drugs.
- 4.13. (Human resources available, inspection frequency for local and international companies)
- 4.14. Provide the number of GMP inspections actually conducted for local and international manufacturers the last three years?
- 4.15. How many government inspectors are there?
- 4.16. Indicate which drug facilities are inspected and indicate the regularity/frequency of the planned inspections:
- 4.16.1. Private pharmacies
 - 4.16.2. Private warehouses
 - 4.16.3. Public sector pharmacies
 - 4.16.4. Public sector warehouse
 - 4.16.5. Hospital storerooms
- 4.17. In the last year how many of each type of drug facility above were actually inspected?
- 4.18. Are storage conditions at port of entry to the country and received warehouse inspected?
- 4.19. Are there any regulations on ethical promotion/advertisement of medicines?
- 4.20. Is there a formal drug problem reporting system? If yes:
- 4.20.1. Briefly describe procedures for reporting and feedback of quality problems and other data.
 - 4.20.2. Provide the number of quality problems and patient adverse drug reactions (ADR) reported about anti-TB drugs.
 - 4.20.3. Provide the number of quality problems and ADRs reported about all essential drugs.
 - 4.20.4. For each reported quality problem or ADR describe the problem and action taken.
 - 4.20.5. Have there been any drug recalls by manufacturers in the last three years?
 - 4.20.5.1. Which drugs?
 - 4.20.6. In the event of manufacturer drug recalls describe the procedure for carrying out the procedures in the health system
- 4.21. What do interviewees consider important to be addressed in drug policy, legislation, regulation and registration of pharmaceutical products?**

Tuberculosis Control Program Drug Management Information System Assessment

Section 5. Selection, Quantification and Procurement

Documents Required: National Essential Drug List; local, national and/or institutional formularies; TB standard treatment guidelines; national and/or local procurement regulation and laws; TB drug procurement specifications; written procedures on batch testing (for new products or suppliers); description of formal drug problem reporting system.

Key indicators:

- Use of EDL in selection of drugs
- Percentage of TB health facilities with a copy of the official MOH standard treatment guideline for TB
- Use of appropriate methodology for TB drug quantification
- TB drug safety stock level (days)
- Percentage of median international price paid by MOH and local health authorities for tracer drugs

Respondents: Key national level agencies – MOH, National Medicine Agency, Institute of Tuberculosis

Name	Agency	Title

5.1. Selection

- 5.1.1. What is the frequency, reliability, necessity of current information exchange for selection, quantification, procurement and quality assurance, between themselves and other relevant agencies?
- 5.1.2. Is there an official national essential drugs list?
- 5.1.3. Is there an official national formulary used in drug selection?
- 5.1.4. Who is responsible for maintaining, updating, and dissemination of the EDL?
- 5.1.5. How often is it reviewed?
- 5.1.6. What information is necessary to support the inclusion of a drug on the list?
- 5.1.7. Who is routinely informed about the EDL or formulary and amendments to the list of drugs it contains? (Are procurement staff?)
- 5.1.8. What national or international reference resources are relevant and available?

- 5.1.9. Who makes drug selection decisions for the TB programme?
 5.1.10. Is drug selection made in compliance with standard treatment guidelines (national or DOTS)?

Data Element	Data Source	Data Collection Level	Institution Collecting Data	Frequency of Data Collection	Quality of Data
EDL at decision making level					

5.2. Quantification

- 5.2.1. Where does the responsibility lie for quantifying TB drug requirements (organization, department, staff title)?
 5.2.1.1. For GDF supplies?
 5.2.1.2. For MOH procurements?
 5.2.1.3. For local level procurements?
- 5.2.2. How often is a quantification exercise undertaken?
- 5.2.3. What methods are used to quantify TB drug requirements (e.g. morbidity-based, consumption-based, adjusted consumption-based, other)?
- 5.2.4. Is the quantification exercise completed manually or computerized?
- 5.2.5. Are estimates subsequently checked against actual use?
- 5.2.6. If consumption-based, does the data refer to quantities dispensed to users or distributed to health facilities?
- 5.2.7. What do they consider to be the minimum/optimal information required to estimate TB drug requirements?
- 5.2.8. Do they take into account stock on hand and losses and adjustments?
- 5.2.9. Where does the information come from (organization, department, etc) that is used in the quantification?
- 5.2.10. How reliable is this information?
- 5.2.11. How is the reliability of the information confirmed?

5.2.12. How is missing data (say consumption reports) compensated for?

5.2.13. What information would they most like to get hold of to assist in quantification that is currently not readily/routinely available?

5.2.13.1. What is the chief constraint to obtaining this information now?

Data Element	Data Source	Data Collection Level	Institution Collecting Data	Frequency of Data Collection	Collection Method	Quality of Data
# of new cases of TB	TB coordinators at judet level	National	TB and Lung Disease Institute	Constantly – promptly after case notification		Unknown
Stock status by drug	TB coordinators at judet level	National	TB and Lung Disease Institute	Quarterly	Telephone	Unknown
Dispensed to user						
STGs						

5.3. Procurement

- 5.3.1. What information is needed during the procurement process?
- 5.3.2. What information on suppliers is routinely maintained or obtained?
- 5.3.3. How is supply performance monitored and recorded?
- 5.3.4. At what levels in the health/administrative system are TB drugs procured?
- 5.3.5. How are procurement quantities determined?
- 5.3.6. Are current inventory levels (at the central warehouse, regional stores, or facilities) taken into account in determining order quantities?
- 5.3.7. Are quantities on order, but not yet received, taken into account?
- 5.3.8. How are lead times taken into account?
- 5.3.9. Is there a safety stock or a buffer stock taken into account?
- 5.3.10. Are losses and adjustments taken into account?
- 5.3.11. Who is responsible for providing/obtaining all information for procurement?
- 5.3.12. What are all the sources of information used during procurement process?
- 5.3.13. How is the absence of key information handled?
- 5.3.14. What procurement methods are used to obtain TB drugs (ICB, LIB, request for quotations, procurement agency, direct negotiations, etc.)?
- 5.3.15. Do you pre-qualify suppliers and/or products?

Data Element	Data Source	Data Collection Level	Institution Collecting Data	Frequency of Data Collection	Quality of Data
Stock on hand					
GMP certification					

5.4. Quality Assurance in Procurement

5.4.1. What information is required from suppliers/manufacturers for pre- or post-qualification?

5.4.1.1. How is this information verified?

5.4.1.2. What certification is required and how is it verified?

Data Element	Data Source	Data Collection Level	Institution Collecting Data	Frequency of Data Collection	Quality of Data

Tuberculosis Control Program Drug Management Information System Assessment

Section 6. Distribution, Transport, Inventory Management and Drug Availability

Documents Required: Drug inventory procedures manual; copies of inventory management forms and receipts; copies of data collection forms for computerized data entry; copies of routine reports on stock inventory and distribution

Key indicators:

- Existence of a distribution plan
- Existence of a process to review and verify requisitions
- Average time between requisition and receipt of TB drugs from stores to facilities
- Adequate storage for TB drugs
- The average percentage of a set of unexpired tracer TB drugs available in health facilities (public pharmacies).
- The percentage of time out-of stock of tracer drugs in health facilities, and public pharmacies.
- The average percentage of stock records that correspond with physical counts for a set of DMTB tracer drugs in TB facilities.

Respondents: Key national level agencies – MOH, National Medicine Agency, Institute of Tuberculosis; Parliament Committee on Health (if any)

Name	Agency	Title

6.1. Distribution

- 6.1.1. Can the distribution system be classified as a “pull” (requisition) or “push” (imprest) system, or a combination of both?
- 6.1.2. If “pull”: who is responsible for initiating the order on the higher level?
- 6.1.3. What information is used to determine the order quantity?
- 6.1.4. What information does the issuing authority use to verify the reasonableness of the requisition or order?

- 6.1.5. If “pull”: who is responsible for initiating the shipment to the lower level?
- 6.1.6. What information is used to determine the consignment quantity?
- 6.1.7. What information does the issuing authority use to verify the reasonableness of the requisition or order?
- 6.1.8. What forms are used to monitor the physical stock transaction, during the process of assembly of consignment to receipt by ordering unit?
- 6.1.9. What is the frequency of re-supply? (i.e. how often are orders placed, distribution of stock undertaken?)
- 6.1.10. Is the quantity ordered or distributed verified with regard to TB caseload?
- 6.1.11. What is the frequency of reporting on distribution and from whom to whom?
- 6.1.12. How accurate is reporting?
- 6.1.13. Are reports received in a timely manner, in accordance with schedules?
- 6.1.14. Is feedback given on reports?

Data Element	Data Source	Data Collection Level	Institution Collecting Data	Frequency of Data Collection	Quality of Data
Requisition					

6.2. Transport

- 6.2.1. How are commodities transferred from central store to judet level facilities?
- 6.2.2. How are drugs transferred from judet hospital to next level in system?
- 6.2.3. How are transportation costs financed? (Centrally or de-centralised?)

6.3. Is lack of transport an issue?

Data Element	Data Source	Data Collection Level	Institution Collecting Data	Frequency of Data Collection	Quality of Data

6.4. Inventory Management

- 6.4.1. What inventory management system is in place: e.g. FEFO, FIFO, other?
- 6.4.2. What records are kept and what data does each record maintain at each storage or distribution point? (e.g. bin card, stock book, computer application, etc)
- 6.4.3. What documentation is used, and what information is contained in each document, to record the issue, dispatch, transfer, and receipt of drugs from one storage facility to another or to a health facility? (e.g. GRN—goods received note; PO—purchase order; IV—issue voucher, etc).
- 6.4.4. Who has authority to sign a requisition, or to issue drugs from a store, or to acknowledge receipt of deliveries?
- 6.4.5. Is there appropriate infrastructure for central and intermediary warehouses, and facility stores?

Data Element	Data Source	Data Collection Level	Institution Collecting Data	Frequency of Data Collection	Quality of Data
Stock on hand					
Receipts					
Issues					
Losses					
Expiration dates (lot)					
# of days out of stock					

6.5. Drug Availability

- 6.5.1. What is the availability of drugs for TB patients in health facilities?
 - 6.5.1.1. first-line drugs
 - 6.5.1.2. second-line drugs
 - 6.5.1.3. drugs to treat common ADRs
 - 6.5.1.4. non-antimicrobial drugs
 - 6.5.1.5. drugs for "supportive" therapy
- 6.5.2. Are stock-out routinely reported and to whom?
- 6.5.3. Are stocks routinely transferred between facilities that are over-stocked and those under-stocked?

Data Element	Data Source	Data Collection Level	Institution Collecting Data	Frequency of Data Collection	Quality of Data

Tuberculosis Control Program Drug Management Information System Assessment

Section 7. Anti-TB Drugs Rational Use

Documents Required: Quarterly and Annual reports (health statistics, pharmaceutical statistics)

Key Indicators

- The percentage of patients diagnosed with TB that are not treated according to official STGs in health facilities.
- Average number of drugs prescribed to inpatient per TB case category per stage of treatment.
- Percentage of TB drugs prescribed with correct dosage and dosage strength (according to official STGs).
- Percentage of prescribed TB drugs that are actually dispensed in the health facilities (to in- and out-patients separately).
- Percentage of TB drugs dispensed with the correct quantity of medication to complete the standard course of therapy (in-patients).
- Percentage of TB drugs dispensed with the correct quantity of medication to complete the therapy in between clinic visits (out-patients).
- Average cost of drugs prescribed and dispensed per case of TB as a percentage of costs if international norms of treatment were followed (DOTS).
- Percentage of TB outpatients prescribed injections at TB facilities

Respondents: Key national level agencies – MOH, National Medicine Agency, Institute of Tuberculosis; sample of health facilities; TB patients

Name	Agency	Title

7.1. What are the prescribing practices in the health facilities that treat TB patients?

7.2. Does prescribing match the STGs for TB (National, local, DOTS)?

7.3. What is the extent and types of supportive therapy given to TB patients?

7.4. What are the significant health and cost implications of prevailing prescribing practices to patients in health facilities, and public pharmacies?

7.5. What are the significant cost implications of prevailing prescribing practices to health facilities, and public pharmacies?

7.6. Observations only:

7.6.1. What is the percentage of health workers who told patients about possible side effects of TB drugs and what to do if signs occur?

7.7. What is the percentage of outpatients who could correctly describe what drugs and why they were prescribed, and implications of interrupted treatment (exit pool interviews, if possible)

Data Element	Data Source	Data Collection Level	Institution Collecting Data	Frequency of Data Collection	Quality of Data
Prescription guidelines					
Actual prescription patterns					
Actual drugs in use					
Drug availability					
Patient adherence/patient treatment cards					
Drug waste/loss					
Other data, please specify:					

Tuberculosis Control Program Drug Management Information System Assessment

Section 8. Anti-TB Drugs Quality Assurance

Documents Required: Quarterly and Annual reports (health statistics, pharmaceutical statistics)

Key Indicators:

Respondents: Key national level agencies – MOH, National Medicine Agency, Institute of Tuberculosis; sample of health facilities; TB patients

Name	Agency	Title

- 8.1. Does the MOH have an active drug product testing system?
- 8.2. Describe the laboratory resources: staff capacity, equipment, record systems, access to reagents, reference standards etc.
- 8.3. What type of quality control testing is done. Physical inspection, laboratory analysis, other
- 8.4. Indicate which of the following pharmaceutical quality control tests are performed on domestic and imported drug samples:
 - 8.4.1. Identity
 - 8.4.2. Potency
 - 8.4.3. Stability
 - 8.4.4. Dissolution
 - 8.4.5. Pyrogen (for injectables)
- 8.5. Provide the number of drugs submitted for testing
- 8.6. Provide the number of drug tests actually tested and the results, indicating reason for failure if any. Obtain lists/reports if available
- 8.7. Indicate the type of laboratory used:
 - 8.7.1. Reference laboratory out of country
 - 8.7.2. National laboratory
 - 8.7.3. University laboratory
 - 8.7.4. Other _____

- 8.8. Is there a formal drug problem reporting system? If yes:
- 8.9. Briefly describe procedures for reporting and feedback of quality problems and defective products
- 8.10. provide the number of quality problems and patient adverse drug reactions (ADRs) reported about TB drugs
- 8.11. provide the number of quality problems and ADRs reported about all essential drugs
- 8.12. for each reported quality problem or ADR describe the problem and action taken
- 8.13. When a drug product has failed quality control testing, what procedure is used for the remaining product in the health system? Describe.
- 8.14. Have any counterfeit products (TB or essential drugs) been detected in the public sector or private sectors in the last three years? Please explain.
- 8.15. How are drug recall procedures handled in the event a manufacturer reports the need to recall a drug product?
- 8.16. Provide a list of all recalled products within the last 3 years
- 8.17. What do you consider the major weaknesses in your quality assurance program?
- 8.18. Drug Donations
 - 8.18.1. What is the value of donated anti-TB drugs received? See attached data sheet for recording donated drug information.
 - 8.18.2. Is there a policy on receiving drug donations? If yes, what does the policy regarding donations of drugs and supplies address:
 - 8.18.2.1. Prior consent from receiver
 - 8.18.2.2. Conformance with national or program formulary
 - 8.18.2.3. Presentation, strength and formulation
 - 8.18.2.4. Quality assurance criteria
 - 8.18.2.5. Package type, size and labelling
 - 8.18.2.6. Shelf life remaining
 - 8.18.2.7. Quantity of each drug
 - 8.18.2.8. Payment of transportation, storage costs and port clearance
 - 8.18.2.9. Other(specify)
 - 8.18.3. Does the program have control over what drugs and supplies will be accepted?

8.19. Licensing, Inspection, and Control

8.19.1. Do mechanisms exist for the licensing/ inspection/ and control of pharmaceutical personnel and for manufacturing, distribution, and dispensing facilities?

8.19.2. Do inspectors use a checklist for inspecting different types of pharmaceutical establishments?

8.19.3. How many inspections were made during each of the last three years for the different types of pharmaceutical establishments?

8.19.4. Is there an audit system to evaluate the inspection system?

Data Element	Data Source	Data Collection Level	Institution Collecting Data	Frequency of Data Collection	Quality of Data
Drug quality control guidelines					
GMP certification					
Certification of packaging					
Pre-registration drug quality testing					
Drug control of drugs supplied					
Warehouse drug quality control					
Drug control in use					
Other data, please specify					

Tuberculosis Control Program Drug Management Information System Assessment

Section 9. Drug Management Information and Information Systems

Documents: Diagram of information systems; lists of indicators; information management plan; data collection forms; MIS feedback reports; donor reports; reporting and data collection schedules; training schedules

Key Indicators:

Use of TB drug management information indicators for decision-making
Existence of information management system; existence of supervisory system, including checklists and feedback reports
Existence of training manual, operations manual and job aids for information management
Existence of forms that collect key DMIS data elements
Percent of facilities/warehouses that keep accurate data required for inventory management
Percent of facilities/warehouses that have submitted an accurate DMIS (or any kind of drug management information) report for the most recent reporting period

Respondents:

Name	Title	Institution

Organizational Structure; Supervision; Planning and Management; Budget

[Interviewer: Using the following questions, determine the roles and functions of key staff responsible for the management of information at all levels of the system. Fill in the table below.]

- 9.1. Is there an institution/unit(s) responsible for managing any health information systems?
- 9.2. Is there a unit responsible for compiling and reporting data on health status and system performance?
- 9.3. What institution/unit(s) are responsible for managing TB program data?
- 9.4. Who is responsible for oversight of TB program data and reporting?

9.5. To what extent is the collection & analysis of data decentralized? Please describe.

9.6. Who are the key staff involved in collecting, compiling, analyzing, disseminating and using drug management information at all levels (e.g., nurse at health facility level is responsible for recording stock levels and reporting end-of-month balances)?

9.7. What are their main responsibilities?

Institution/Unit & Level	Key Staff Position	Info Mgt Responsibility

9.8. Is there a budget for any drug management information system functions (e.g., computers, software, printing of forms and records)?

9.9. Is there a supervisory system in place that oversees the quality of management information?

9.10. Does the TB program strategy include a plan for information management?
[Interviewer: obtain a copy]

9.11. Is there a unit responsible for training and continuing education of staff in the area of information management? Do information management training plans exist?

9.12. Do manuals and/or job aids regarding information management exist? If so, who uses them (at what levels in the system)?

9.13. Existing Management Information Systems

9.13.1. What organized 'information systems' exist within the health sector?

9.13.2. Who is responsible for managing these systems?

9.13.3. What type of information is collected and compiled by these systems?

9.13.4. Are any of these systems automated? If yes, which levels are automated and which levels are manual?

9.13.5. Who are the key information audiences and users of data on drug management? Have their needs for information related to management decisions been specified?

9.13.6. Map of Information Flow (Collection, Aggregation, Reporting and Feedback)

9.14. *[Interviewer: Using the following questions to obtain information, draw a diagram depicting information flow. Diagram the network of information depicting how and where information sources are integrated, collected, compiled, analyzed, disseminated and use .]*

9.14.1. What health programs are covered by the information systems?

9.14.2. What is the information flow of these health information systems?

9.14.3. How many levels exist in the system?

9.14.4. How are the data collection forms categorized?

9.14.5. Which facilities have to report?

9.14.6. Where does data get aggregated and/or compiled?

9.14.7. What type of reports exists?

9.14.8. What kind of feedback is given to managers at all levels?

9.15. Flexibility

9.15.1. How does the information system respond to changes in demand?

9.15.2. How does supply flow respond to changes in demand (does information reach higher levels?)

9.15.3. How does the information system respond to growth/ reduction in services?

9.15.4. Are the forms pre-printed?

9.15.5. How often do forms get reproduced?

9.15.6. How often are the forms updated to reflect changes in drug supply and management (e.g., changes in drug selection, STGs, protocols, etc.)?

9.16. Integration

9.16.1. What programs are covered by the information systems? Does the same system cover more than one vertical program (e.g., family planning, immunization, TB)?

9.16.2. Do the forms contain information on different programs?

9.17. Representativeness

9.17.1. What percentage of public health facilities (of all types - hospitals, warehouses, clinics, etc.) are required to fill out standardized forms and send in standard reports?

9.17.2. Of the number of facilities required to send reports, what percentage reports information in a timely manner?

9.18. Data Quality

(Note: insert questions on accuracy, timeliness, completeness, gaps in data availability)

9.18.1. Is the quality of data entered into forms validated? Is the quality of reports validated against original data sources?

9.18.2. Are physical inventories conducted?

9.18.2.1. How often?

9.18.2.2. What is inventoried?

9.18.2.3. Are inventories registered?

9.18.3. Are stock registers cross-checked against physical counts?

9.18.4. How accurate are reports received from health facilities? [Interviewer: get an idea of the key informant's perception of accuracy since exact data may not exist]

9.18.5. If there is a reporting schedule, how many facilities reported on-time in the last reporting period? [Interviewer: get an idea of the key informant's perception of accuracy since exact data may not exist]

9.19. Sources of Data and Information

9.19.1. With regard to TB, what are the main sources of the following data types in the public sector? :

9.19.2. Demographic, Epidemiological and Morbidity Data:

9.19.3. Service Utilization:

9.19.4. Dispensed-to-User (Consumption) Data:

9.19.5. Distribution and Inventory Management:

9.19.6. Drug Availability:

9.19.7. Drug Use Practices:

9.19.8. Duplication of Data:

9.19.9. Data Elements [Interviewer: Refer to Spreadsheet A)

9.19.10. Data Collection Forms [Interviewer: Refer to Spreadsheet B)

9.19.11. Is there a schedule for report preparation, data transmission and feedback reporting? [Interviewer: obtain or document the schedule]

9.19.12. How many data collection forms exist? What kind of information is recorded? [Interviewer: complete Excel spreadsheet; get a copy of all relevant forms]

9.19.13. Do staff use any data to complete report forms before sending them to higher levels?

9.19.14. Are data collection forms and reports standardized? Are instructions available for completing them?

9.19.15. What is the process of data collection? How often do lower levels record and report data?

9.19.16. How long does it take staff to fill in the reporting forms each month, quarter, and year?

[Interviewer: Determine whether data collection methods are appropriate for the types of data being collected; whether time spent on reporting can be reduced; whether data collection process can be streamlined.]

9.19.17. Are there any overlaps in data being reported at different levels? Are any types of data collected that are never used?

9.19.18. Are feedback reports provided routinely to the units that collected the data? Do they incorporate graphic as well as tabular information?

9.19.19. Are there any incentives (monetary or non-monetary) provided for staff to complete forms and reports in an accurate and timely manner?

9.20. Data Compilation and Analysis

9.20.1. What are the responsibilities of the following for data compilation and analysis?

9.20.1.1. NTP

9.20.1.2. TB Institute

9.20.1.3. District (oblast/rayon/judet?)

9.21. Feedback, Dissemination and Use of Use of Data for Decision-Making at Different Levels

9.22. Management Information Needs

9.23. Monitoring and Evaluation

- 9.23.1. Are there any indicators that are monitored by these systems? If so, what are they? [Interviewer: obtain a list] If so, how are indicators used to make decisions regarding drug management and availability?

9.24. Existing Reports, Reporting Requirements and Periodicity of Reporting

9.25. Computers

- 9.25.1. Is any data regarding the TB program (eg., drug management, epidemiology, morbidity, etc.) entered or compiled using a computer? At what levels of the system is a computer used (e.g., hospital, clinic, warehouse, etc.)? Please describe the automated processes.

- 9.25.2. What kind of software is used to enter or compile data?

9.26. Electricity

9.27. Electronic Transfer of Data and Telephone Communications

- 9.27.1. How many telephone/cell phone companies operate in the country? List the names of the top five companies in order of relative importance.
- 9.27.2. How much of the country is supplied by at least one telephone company?
- 9.27.3. Which areas of the country have no access to telephone connections?
- 9.27.4. Is the telephone system considered to be very reliable? What are some of the problems typically encountered?
- 9.27.5. Internet Providers
- 9.27.6. How many internet providers are there in the country? List the names of the top three companies in order of relative importance.
- 9.27.7. What is the average bandwidth available for businesses wanting internet access? Are there any other issues to be aware of with respect to internet access?